



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: Weers et al.                     | Group Art Unit: 1617                          |
| Application No: 09/851,226                             | Examiner: HUI, San Ming R.                    |
| Confirmation No: 4017                                  | Attorney Docket No:                           |
| Filed: May 8, 2001                                     | 0073.00                                       |
| Title: PHOSPHOLIPID-BASED<br>POWDERS FOR DRUG DELIVERY | October 26, 2007<br>San Francisco, California |

### COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

VIA ELECTRONIC FILING

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Examiner Hui:

This Comments on Statement of Reasons for Allowance is responsive to the "Reasons for Allowance" provided by the Examiner in the Notice of Allowability attached to the Notice of Allowance and Fees Due statement mailed on April 17<sup>th</sup>, 2007.

#### CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450; or facsimile transmitted to the U.S. Patent and Trademark Office at (571) 273-8300; or electronically filed via PAIR, on the date shown below.

By: \_\_\_\_\_

  
Alison R. Parker

Date: 10/26/07

## REMARKS

Applicant notes with appreciation the indication of allowance of all of the pending claims. The following comments are being provided to clarify the language provided in the Statement of Reasons For Allowance.

In the Reasons For Allowance, the Examiner stated:

Applicant's remarks with regard to the ratio of the polyvalent ions recited in the claims not being taught or fairly suggested by the cited prior arts have been considered, and are found persuasive to withdraw the outstanding rejection. Only the secondary reference teaches the addition of divalent ion (calcium salts) to stabilize the phospholipid composition; however, the ratio taught in Materne is about 10 times more than what is disclosed in the instant specification. Given the superiority of the phospholipid composition by adding the polyvalent ions, the rejection under 35 USC 103(a) is withdrawn.

Applicant agrees with the Examiner's conclusion that independent claim 1, for example, is not rendered unpatentable under 35 U.S.C. §103(a) by Weers et al. (US patent no. 6,309,623) in view of Materne et al. (GB patent no. 2,065,659). A particulate composition for delivery to the pulmonary system comprising particles having a molar ratio of polyvalent cation to phospholipid that is at least 0.05 and is sufficiently high to increase the gel-to-liquid crystal transition temperature of the particles compared to particles without the polyvalent cation such that the particles have a gel-to-liquid crystal transition temperature that is greater than room temperature by least 20°C is not taught by the references singly or in combination.

As explained in the Appeal Brief, the primary reference, Weers et al., does not disclose that a polyvalent cation can be used to increase the gel-to-liquid transition temperature of a phospholipid, and does not disclose that such a combination is desirable to achieve a higher gel-to-liquid transition temperature. Weers et al. also does not disclose the molar ratio recited in the claim. Materne

et al. does not make up for the deficiencies of Weers et al. because Materne et al. does not teach or suggest a molar ratio of polyvalent cation to phospholipid ratio that is at least 0.05 and is sufficiently high to increase the gel-to-liquid crystal transition temperature of the particles that is greater than room temperature by least 20°C. Instead, Materne et al. recites the following:

The amount of calcium chloride added to the phosphatidylcholine is chosen such that the molar ratio of phosphatidylcholine to calcium chloride is between 1:05 and 1:2 and preferably 1:0.5, i.e., that 0.5 to 2 moles of calcium chloride are subjected to reaction with each mole of phosphatidylcholine. (Page 1 lines 107-113).

Materne et al. does not teach that the ratio must be sufficiently high to increase the gel-to-liquid crystal transition temperature of the particles, as recited in the claims. Furthermore, any particles that result from the teachings of Materne et al. are devoid of the active agent element recited in the claims (note that Materne et al. teaches a process for making pure calcium phosphatidylcholine chloride), and the presence of an active agent in the particles will affect the characteristics of the particle. Accordingly, the addition of an amount of polyvalent cation that is sufficiently high to increase the gel-to-liquid crystal transition temperature of particles containing an active agent is not taught by either Weers et al. or by Materne et al., and the claims are therefore allowable as recognized by the Examiner.

Furthermore, the unexpected results achieved by the present invention are further evidence of the nonobviousness of the invention. These unexpected results are described throughout the specification and in the Appeal Brief.

For at least these reasons, claim 1 is not properly rejectable under 35 USC §103(a) as being unpatentable over Weers et al. and Materne et al. There is no modification to Weers et al that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made that would result in the invention of claim 1. Furthermore, there is no indication that the

teachings of Materne et al. could be applied to the teachings of Weers et al. with a reasonable likelihood of arriving at the invention of claim 1 or with a reasonable likelihood of success. This lack of teaching, lack of combinability and the unexpected results found by Applicant illustrate how claim 1 is allowable over the references cited. Since neither Weers et al. nor Materne et al teaches all features of claim 1 and since the invention achieves unexpected results, claim 1 is allowable over the references.

Furthermore, the other independent claims, which are each self-standing, are allowable because the language recited in each of the claims themselves is allowable over the prior art.

The Examiner is respectfully requested to consider Applicant's Comments on Examiner's Reasons for Allowance and is requested to respond to these comments if there is disagreement or additional clarification needed. In view of the present clarification, the language of the Reasons for Allowance should not be used to limit the scope of the allowed independent claims.

## Conclusion

Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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